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10/083,938	02/27/2002	George Worthley	GEM-P-02-001	8384

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PATENTS+TMS
A Professional Corporation
1914 North Milwaukee Avenue
Chicago, IL 60647

EXAMINER

LEWIS, KIM M

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 03/02/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/083,938

Applicant(s)

WORTHLEY, GEORGE

Examiner

Kim M. Lewis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 February 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/4-2-02.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Detailed Action.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 4/3/02 has been received and made of record in the application file wrapper. Note the acknowledged form PTO-1449 enclosed herewith.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: "23" is missing from the specification but shown in Fig. 1. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,124,521 ("Roberts") in view of U.S. Patent Nos. 5,980,497 ("Yavitz") and 6,592,888 ("Jensen et al.").

As regards claim 1, Roberts substantially discloses the claimed invention. More specifically, Roberts discloses a semi-permeable film (20) having a top side and a bottom side, a tape border (12) having a top surface (16), a bottom surface (14), a first edge and a second edge wherein the semi-permeable film covers the top surface of the semi-permeable tape border, and an adhesive associated with the bottom surface of the semi-permeable tape border wherein the adhesive forms a barrier (col. 1, lines 54-59 and col. 3, lines 25-30). Roberts is silent as to the permeability of the tape, and fails to teach hydrocolloid silver adhesive.

Yavitz teaches that it is conventional to construct dressings from impermeable or semi-permeable cloth/fabric tape depending upon the intended use (col. 3, lines 24-42). Therefore, it would have been obvious to one having ordinary skill in the art, at the time the invention was made, to construct the cloth/fabric tape layer from semi-permeable material in order to allow the moisture from the skin of the user to evaporate.

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As to the hydrocolloid silver adhesive, Jensen et al. teach it is conventional in the art to provide wound dressings with adhesive material comprising both hydrocolloid material and silver because hydrocolloids are highly absorbent and silver is an anti-microbial agent that kills bacteria (col. 3, line 26-col. 4, line 41).

In view of Jensen et al., it would have been obvious to one having ordinary skill in the art to modify Roberts by substituting the adhesive layer for a hydrocolloid adhesive because hydrocolloids are highly absorbent and silver is an anti-microbial agent that kills bacteria. Such a substitution requires only routine skill in the art.

As regards claim 2, note adhesive layer (22) on the bottom side of the semi-permeable film.

6. Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roberts in view of Yavitz and Jensen et al. **(Alternate Rejection)**.

As regards claims 1, 2 and 3, Roberts substantially discloses all features of the claims including a semi-permeable film (20) having a top side and a bottom side, a tape border (12) having a top surface (16), a bottom surface (14), a first edge and a second edge wherein the semi-permeable film covers the top surface of the semi-permeable tape border, an adhesive (14) associated with the bottom surface of the semi-permeable tape border wherein the hydrocolloid adhesive forms a barrier (col. 1, lines 54-59 and col. 3, lines 54-59), and an adhesive coating (22) on the bottom side of the semi-permeable film. Roberts additionally discloses an absorbent fiber layer (26) and a non-adherent porous film layer (30) secured thereto. The fiber layer provides moisture

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absorption and serves as a cushion, while the non-adherent porous film layer prevent the absorbent layer from sticking to the wound upon removal.

Roberts fails to teach the permeability of the tape layer hydrocolloid silver adhesive.

Yavitz teaches that it is conventional to construct dressings from impermeable or semi-permeable cloth/fabric tape depending upon the intended use (col. 3, lines 24-42). Therefore, it would have been obvious to one having ordinary skill in the art, at the time the invention was made, to construct the cloth/fabric tape layer from semi-permeable material in order to allow the moisture from the skin of the user to evaporate.

As to the hydrocolloid silver adhesive, Jensen et al. teach it is conventional in the art to provide wound dressings with hydrocolloid silver adhesive material because hydrocolloids are highly absorbent and silver is an anti-microbial agent that kills bacteria (col. 3, line 26-col. 4, line 41).

It would have been obvious to have been obvious to one having ordinary skill in the art to modify Roberts by substituting the absorbent fiber layer, including the porous non-adherent film, for a hydrocolloid silver adhesive layer, since hydrocolloid silver adhesive material is highly absorbent, kills bacteria and/or prevents the growth thereof, and it does not adhere to wounds upon removal. This substitution provides the added benefit of an antimicrobial activity to the dressing.

As to claim 4, Roberts teaches a first liner (40) covering the adhesive layer opposite the semi-permeable tape border and covering the hydrocolloid silver adhesive wherein the first liner extends from the first edge of the semi-permeable tape border to a

first location between the first edge of the semi-permeable tape border and the second edge of the semi-permeable tape border.

As regards claim 5, note the tab on first liner (40) in Fig. 2.

As regards claims 6, as can be seen from Fig. 2, Roberts discloses a second liner covering the adhesive layer opposite the semi-permeable tape border and covering the hydrocolloid silver adhesive.

As regards claim 7, note the openings/windows cut substantially through the semi-permeable tape border, the absorbent fiber layer and the porous non-adherent film layer. Once modified to include the hydrocolloid silver adhesive, the dressing of Roberts will maintain this configuration.

As regards claim 8, the openings/windows defines a perimeter around a wound (catheter access site).

As regards claims 9 -11, the film is moisture vapor permeable, transparent and constructed from polyurethane (col. 3, lines 31-41).

As regards claim 12, note the reference to a zeolite at col. 4, lines 28-42 of Jensen et al.

As regards claim 13, Roberts discloses that the tape border is a non-woven fabric tape layer. Roberts is silent as to the lamination of the tape border and the film layer. Instead, Roberts discloses that the two layers are adhered to one another via adhesive (22). The examiner, however, contends that it would have been *prima facie* obvious to one having ordinary skill in the art to use any conventionally known securing means (e.g., laminating, gluing, heat sealing, etc.) to secure the film layer to the tape

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border. Additionally, absent a critical teaching, the examiner wishes the applicant to note that the means by which the film layer is secured to the tape border is an obvious design choice, which does not patentably distinguish applicant's invention.

As regards claims 14-18, the claimed method of applying a dressing is accomplished by mere usage of the modified dressing of Roberts as discussed in the rejection of claims 1 and 3-12.

As regards claims 19-22, the claimed process of the manufacture of a dressing is accomplished by mere manufacturing of the modified dressing of Roberts as discussed in the rejection of claims 1 and 3-12.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is 703.308.1191. The examiner can normally be reached on Monday to Wednesday from 5:30 am to 4:00 pm.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kim M. Lewis
Primary Examiner
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Kml

February 18, 2004